

Customer No. 26308

PATENT

15992 U.S. PTO



10/01/03

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

22264 U.S. PTO

10/676815



10/01/03

## NEW APPLICATION TRANSMITTAL Under 37 CFR § 1.53(b)

Transmitted herewith for filing is the patent application of

Inventor(s): **JOHN A. MACOVIK; ROBERT T. CHANG; DAVID A. RAHDERT;  
TIMOTHY R. MACHOLD; and RICK A. SOSS**

**WARNING:** 37 C.F.R. § 1.41(a)(1) points out:

(a) A patent is applied for in the name or names of the actual inventor or inventors.  
(1) The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by § 1.63, except as provided for in § 1.53(d)(4) and § 1.63(c). If an oath or declaration as prescribed by § 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to § 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in § 1.17(i) is filed supplying or changing the name or names of the inventor or inventors.

For (title): **DEVICES, SYSTEMS, AND METHODS FOR SUPPLEMENTING,  
REPAIRING, OR REPLACING A NATIVE HEART VALVE LEAFLET**

1. **Type of Application**  
This new application is for a(n)  
☒ [X] Original (nonprovisional)  
☐ [ ] Design  
☐ [ ] Plant

**NOTE:** If one of the following 3 items apply then complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED and a NOTIFICATION IN PARENT APPLICATION OF THE FILING OF THIS CONTINUATION APPLICATION.

- ☐ [ ] Divisional.  
☐ [ ] Continuation.  
☐ [ ] Continuation-in-part (C-I-P).

2. **Benefit of Prior U.S. Application(s) (35 U.S.C. 119(e), 120, or 121)**  
☒ [X] The new application being transmitted claims the benefit of prior U.S. application(s). Enclosed are ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

## CERTIFICATION UNDER 37 C.F.R. 1.10\*

I hereby certify that this New Application Transmittal and the documents referred to as attached therein are being deposited with the United States Postal Service on this date 1 OCTOBER 2003, in an envelope as 'Express Mail Post Office to Addressee' mailing Label Number EV317559361US, addressed as follows: Mail Stop Patent Application, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450

Judith Dunaway

(type or print name of person mailing paper)

Signature of person mailing paper

(Application Transmittal - page 1 of 5)

**3. Papers Enclosed**

A. Required for filing date under 37 C.F.R. § 1.53(b) (Regular) or 37 C.F.R. § 1.153 Design Application

<u>22</u>	Pages of specification
<u>04</u>	Pages of claims
<u>01</u>	Abstract
<u>09</u>	Sheets of drawing
<input type="checkbox"/> [ x ]	formal
<input type="checkbox"/> [ ]	informal

B. Other documents enclosed: \_\_\_\_\_

**4. Additional papers enclosed**

- ☐ [ ] Preliminary Amendment
- ☐ [ ] Information Disclosure Statement (37 C.F.R. 1.98)
- ☐ [ ] Form PTO-1449 (PTO/SB/08A and 08B)
- ☐ [ ] Citations
- ☐ [ ] Declaration of Biological Deposit
- ☐ [ ] Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence.
- ☐ [ ] Authorization of Attorney(s) to Accept and Follow Instructions from Representative
- ☐ [ ] Special Comments
- ☐ [ ] Other

**5. Declaration or oath**

- ☐ [ ] Enclosed
  - ☐ [ ] newly executed
  - ☐ [ ] copy from parent application identified above
- Executed by (*check all applicable boxes*)
  - ☐ [ ] inventor(s).
  - ☐ [ ] legal representative of inventor(s).
  - ☐ [ ] joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.
  - ☐ [ ] This is the petition required by 37 CFR 1.47 and the statement required by 37 CFR 1.47 is also attached. See Item 13 below for fee.
- ☒ [ x ] Not Enclosed.
  - ☒ [ x ] Application is made by a person authorized under 37 C.F.R. 1.41(c) on behalf of all the above named inventor(s). (The declaration or oath, along with the surcharge required by 37 CFR 1.16(e) can be filed subsequently).

**6. Inventorship Statement**

The inventorship for all the claims in this application are:

- ☒ [ x ] The same.
- ☐ [ ] Not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made
  - ☐ [ ] is submitted.
  - ☐ [ ] will be submitted.

**7. Language**

- ☒ English  
☐ Non-English  
☐ The attached translation includes a statement that the translation is accurate. 37 C.F.R. 1.52(d).

**8. Assignment**

- ☒ An assignment of the Invention to Ample Medical, Inc.  
☐ is attached. A separate ☐ COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION or ☐ FORM PTO 1595 is also attached.  
☒ will follow.  
☐ was filed in the parent application identified above

**9. CERTIFIED COPY**

Certified copy(ies) of application(s)

Country	Appln. No.	Filed
Country	Appln. No.	Filed
Country	Appln. No.	Filed
Country	Appln. No.	Filed

from which priority is claimed

- ☐ is (are) attached.  
☐ will follow.

**NOTE:** The foreign application forming the basis for the claim for priority must be referred to in the oath or declaration. 37 CFR 1.55(a) and 1.63.

**10. Fee Calculation (37 C.F.R. 1.16)**

- A. ☒ Regular application

CLAIMS AS FILED					
	Number Filed	Number Included in Basic Fee	Number Extra	Rate	Basic Fee 37 CFR 1.16(a) \$770.00
Total Claims 37 CFR 1.16(c)	24	-20 =	4	x \$ 18.00	\$72
Independent Claims (37 CFR 1.16(b))	1	-3 =	(2)	x \$ 86.00	\$0
Multiple Dependent claim(s) if any (37 CFR 1.16(d))				\$290.00	\$0
<b>FILING FEE CALCULATION</b>					<b>\$842</b>

- ☐ Amendment cancelling extra claims enclosed.  
☐ Amendment deleting multiple-dependencies enclosed.  
☐ Fee for extra claims is not being paid at this time.

Filing Fee Calculation

842.00

- B. ☐ Design application  
(\$340.00 - 37 CFR 1.16(f))  
Filing Fee Calculation \_\_\_\_\_
- C. ☐ Plant application  
(\$530.00 - 37 CFR 1.16(g))  
Filing Fee Calculation \_\_\_\_\_

**11. Small Entity Statement**

- ☒ The applicant is a Small Entity as defined by 37 CFR 1.9 and 1.27 and is entitled to small entity status.  
☒ Small Entity Filing Fee: 421.00

**12. Fee Payment Being Made at This Time**

- ☒ Not Enclosed  
☒ No filing fee is to be paid at this time.  
(This and the surcharge required by 37 C.F.R. 1.16(e) can be paid subsequently.)
- ☐ Enclosed
- |   |              |
|---|--------------|
| <input type="checkbox"/> Filing fee   | _____        |
| <input type="checkbox"/> Recording assignment<br>(\$40.00; 37 C.F.R. 1.21(h))   | _____        |
| <input type="checkbox"/> Petition fee for filing by other than all the<br>inventors or person on behalf of the inventor<br>where inventor refused to sign or cannot be<br>reached<br>(\$130.00; 37 C.F.R. 1.47 and 1.17(i)) | _____        |
| <input type="checkbox"/> For processing an application with a<br>specification in a non-English language<br>(\$130.00; 37 C.F.R. 1.52(d) and 1.17(k))   | _____        |
| <input type="checkbox"/> Processing and retention fee<br>(\$130.00; 37 C.F.R. 1.53(d) and 1.21(l))  | _____        |
| <input type="checkbox"/> Fee for international-type search report<br>(\$40.00; 37 C.F.R. 1.21(e))   | _____        |
| <b>Total fees enclosed</b>  | <b>- 0 -</b> |

**13. Method of Payment of Fees**

- ☐ Check in the amount of \$ \_\_\_\_\_.
- ☐ Charge Account No. \_\_\_\_\_ in the amount of \_\_\_\_\_.
- A duplicate of this transmittal is attached.

**14. Authorization to Charge Additional Fees**

- ☐ The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No. \_\_\_\_\_
- |   |
|---|
| <input type="checkbox"/> 37 C.F.R. 1.16(a), (f) or (g) (filing fees)  |
| <input type="checkbox"/> 37 C.F.R. 1.16(b), (c) and (d) (presentation of extra claims)  |
| <input type="checkbox"/> 37 C.F.R. 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application) |
| <input type="checkbox"/> 37 C.F.R. §§ 1.17(a)(1-5) (extension fees pursuant to § 1.136(a)).   |
| <input type="checkbox"/> 37 C.F.R. 1.17 (application processing fees)   |
| <input type="checkbox"/> 37 C.F.R. 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. 1.311(b))                                   |

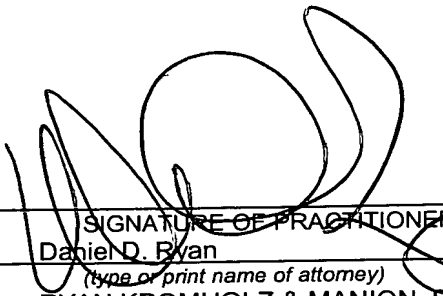
15. Instructions as to Overpayment

- ☐ Credit Account No. \_\_\_\_\_  
☐ Refund

Reg. No. 29,243

Tel. No.: (262) 783 - 1300

Customer No.: 26308

  
\_\_\_\_\_  
SIGNATURE OF PRACTITIONER  
Daniel D. Ryan  
(type or print name of attorney)  
\_\_\_\_\_  
RYAN KROMHOLZ & MANION, S.C.  
(P.O. Address)  
\_\_\_\_\_  
Post Office Box 26618  
\_\_\_\_\_  
MILWAUKEE, WISCONSIN 53226

☒ Statement Where Additional Pages are Added

- ☒ Plus Added Page for New Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed

☐ Statement Where No Further Pages Added

(if no further pages form a part of this Transmittal, then end this Transmittal with this page and check the following item)

- ☐ This transmittal ends with this page.

**ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT  
OF PRIOR U.S. APPLICATION(S) CLAIMED**

NOTE: "In order for an application to claim the benefit of a prior filed copending national application, the prior application must name as an inventor at least one inventor named in the later filed application and disclose the named inventor's invention claimed in at least one claim of the later filed application in the manner provided by the first paragraph of 35 U.S.C. 112." 37 CFR 1.78(a).

NOTE: "IN ADDITION THE PRIOR APPLICATION MUST BE (1) COMPLETE AS SET FORTH IN S 1.51, OR (2) ENTITLED TO A FILING DATE AS SET FORTH IN S 1.53(B) AND INCLUDE THE BASIC FILING FEE SET FORTH IN S 1.16; OR (3) ENTITLED TO A FILING DATE AS SET FORTH IN S 1.53(B) AND HAVE PAID THEREIN THE PROCESSING AND RETENTION FEE SET FORTH IN S 1.21(L) WITHIN THE TIME PERIOD SET FORTH IN S 1.53(D)." 37 CFR 1.78(A).

**16. Relate Back-35 U.S.C. 120**

NOTE: "ANY APPLICATION CLAIMING THE BENEFIT OF A PRIOR FILED COPENDING NATIONAL OR INTERNATIONAL APPLICATION MUST CONTAIN OR BE AMENDED TO CONTAIN IN THE FIRST SENTENCE OF THE SPECIFICATION FOLLOWING THE TITLE A REFERENCE TO SUCH PRIOR APPLICATION IDENTIFYING IT BY SERIAL NUMBER AND FILING DATE OR INTERNATIONAL APPLICATION NUMBER AND INTERNATIONAL FILING DATE AND INDICATING THE RELATIONSHIP OF THE APPLICATIONS." 37 CFR 1.78(A). SEE ALSO THE NOTICE OF APRIL 28, 1987 (1079 O.G. 32 TO 46).

[ X ] The specification includes the following recitation:

**Related Applications:**

This application claims the benefit of co-pending United States Patent Application Serial No. 09/666,617, filed September 20, 2000 and entitled "Heart Valve Annulus Device and Methods of Using Same," which is incorporated herein by reference. This application also claims the benefit of Patent Cooperation Treaty Application Serial No. PCT/US 02/31376, filed October 1, 2002 and entitled "Systems and Devices for Heart Valve Treatments," which claimed the benefit of United States Provisional Patent Application Serial No. 60/326,590, filed October 1, 2001, which are incorporated herein by reference. This application also claims the benefit of United States Provisional Patent Application Serial No. 60/429,444, filed November 26, 2002, and entitled "Heart Valve Remodeling Devices;" United States Provisional Patent Application Serial No. 60/429,709, filed November 26, 2002, and entitled "Neo-Leaflet Medical Devices;" and United States Provisional Patent Application Serial No. 60/429,462, filed November 26, 2002, and entitled "Heart Valve Leaflet Retaining Devices," which are each incorporated herein by reference.

NOTE: THE PROPER REFERENCE TO A PRIOR FILED PCT APPLICATION WHICH ENTERED THE U.S. NATIONAL PHASE IS THE U.S. SERIAL NUMBER AND THE FILING DATE OF THE PCT APPLICATION WHICH DESIGNATED THE U.S.

NOTE: (1) WHERE THE APPLICATION BEING TRANSMITTED ADDS SUBJECT MATTER TO THE INTERNATIONAL APPLICATION THEN THE FILING CAN BE AS A CONTINUATION-IN-PART OR (2) IT IS DESIRED TO DO SO FOR OTHER REASONS, E.G. WHERE NO DECLARATION IS AVAILABLE, NO ENGLISH TRANSLATION IS AVAILABLE OR NO FEE IS TO BE PAID ON FILING THEN THE FILING CAN BE AS A CONTINUATION. IN THESE CASES THE INTERNATIONAL APPLICATION DESIGNATING THE U.S. IS TREATED AS THE PARENT CASE IN THE U.S. AND IS AN ALTERNATIVE TO THE COMPLETION OF THE INTERNATIONAL APPLICATION UNDER 35 U.S.C. 371(C)(4) WHICH MUST MEET THE REQUIREMENTS OF 37 CFR 1.61(A). THIS ALTERNATIVE PERMITS THE COMPLETION OF THE FILING REQUIREMENTS WITHIN ANY TERM SET BY THE PTO UNDER 37 CFR 1.53(D) TO WHICH THE EXTENSION PROVISIONS OF 37 CFR 1.136(A) APPLY. (WHEREAS, IF THE FILING IS AS AN INTERNATIONAL APPLICATION ENTERING THE U.S. STAGE THEN THE FEE, DECLARATION AND/OR ENGLISH TRANSLATION (WHERE NECESSARY) IS DUE WITHIN 20 MONTHS OF THE PRIORITY DATE BUT CAN BE PAID WITHIN 22 MONTHS OF THE PRIORITY DATE (OR IS DUE WITHIN 30 MONTHS OF THE PRIORITY DATE BUT CAN BE SUBMITTED WITHIN 32 MONTHS OF THE PRIORITY DATE) WITH THE SURCHARGES SET FORTH IN 37 CFR 1.492(E), (F) AND 37 CFR 1.495(C); HOWEVER, THE PROVISIONS OF 37 CFR 1.136 DO NOT APPLY TO THIS 22 OR (32 MONTH) PERIOD. 37 CFR 1.61(B).)

NOTE: THE DEADLINE FOR ENTERING THE NATIONAL PHASE IN THE U.S. FOR AN INTERNATIONAL APPLICATION WAS

*"The Patent and Trademark Office considers the International application to be pending until the 22nd month from the priority date if the United States has been designated and no Demand for International Preliminary Examination has been filed prior to the expiration of the 19th month from the priority date and until the 32nd month from the priority date if a Demand for International Preliminary Examination which elected the United States of America has been filed prior to the expiration of the 19th month from the priority date, provided that a copy of the international application has been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively. If a copy of the international application has not been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively, the international application becomes abandoned as to the United States 20 or 30 months from the priority date respectively. These periods have been placed in the rules as paragraph (h) of S 1.494 and paragraph (i) of S 1.495. A continuing application under 35 U.S.C. 365(c) and 120 may be filed anytime during the pendency of the international application."*

**17. Relate Back-35 U.S.C. 119 Priority Claim for Prior Application**

The prior U.S. application(s), including any prior International Application designating the U.S., identified above in item 17, in turn itself claim(s) foreign priority (ies) as follows:

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country	appl. no.	filed on
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The certified copy (ies) has (have)

☐ been filed on \_\_\_\_\_ in prior application \_\_\_\_\_ which was filed on \_\_\_\_.  
☐ is (are) attached

**WARNING:** *The Certified Copy of the priority application which may have been communicated to the PTO by the International Bureau may not be relied on without any need to file a Certified Copy of the priority application in the continuing application. This is so because the certified copy of the priority application communicated by the International Bureau is placed in a folder and is not assigned a U.S. Serial Number unless the national stage is entered. Such folders are disposed of if the national stage is not entered. Therefore such certified copies may not be available if needed later in the prosecution of a continuing application. An alternative would be to physically remove the priority documents from the folders and transfer them to the continuing application. The resources required to request transfer, retrieve the folders, make suitable record notations, transfer the certified copies, enter and make a record of such copies in the continuing application are substantial. Accordingly, the priority documents in folders of international applications which have not entered the national stage may not be relied on.*

**18. Maintenance of Copendency of Prior Application**

**NOTE:** *The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the continuation application.*

**A. ☐ Extension of time in prior application**

☐ A petition, fee and response extends the term in the pending prior application until \_\_\_\_\_.  
☐ A copy of the petition filed in prior application is attached

**B. ☐ Conditional Petition for Extension of Time in Prior Application**

☐ A conditional petition for extension of time is being filed in the pending prior application.  
☐ A copy of the conditional petition filed in the prior application is attached

**19. Further Inventorship Statement Where Benefit of Prior Application(s) Claimed**

**NOTE:** *If the continuation, continuation-in-part, or divisional application is filed by less than all the inventors named in the prior application a statement must accompany the application when filed requesting deletion of the names of the person or persons who are not inventors of the invention being claimed in the continuation, continuation-in-part, or divisional application. 37 CFR 1.62(a)*

NOTE: In the case of a continuation-in-part application which adds and claims additional disclosure by amendment, an oath or declaration as required by § 1.63 must be filed. In those situations where a new oath or declaration is required due to additional subject matter being claimed, additional inventors may be named in the continuing application. In a continuation or divisional application which discloses and claims only subject matter disclosed in a prior application, no additional oath or declaration is required and the application must name as inventors the same or less than all the inventors in the prior application. 37 cfr 1.60(c). (Dealing with the continuation situation).

- (a) ☐ This application discloses and claims only subject matter disclosed in the prior application whose particulars are set out above and the inventor(s) in this application are  
☐ the same.  
☐ the following inventor(s) have been deleted:  
  
☐ the following inventor(s) have been added:
- (b) ☐ This application discloses and claims additional disclosure and a new declaration or oath is being filed. With respect to the prior application the inventor(s) in this application are  
☐ the same.  
☐ the following inventor(s) have been deleted:  
  
☐ the following inventor(s) have been added:
- (c) The inventorship for all the claims in this application are  
☒ the same.  
☐ not the same, and an explanation, including the ownership of the various claims at the time the last claimed invention was made  
☐ is submitted.  
☐ will be submitted.

**20. Abandonment of Prior Application (if applicable)**

- ☐ Please abandon the prior application at a time while the prior application is pending or when the petition for extension of time or to revive in that application is granted and when this application is granted a filing date so as to make this application copending with said prior application.

NOTE: ACCORDING TO THE NOTICE OF MAY 13, 1983 (103, TMOG 6-7) THE FILING OF A CONTINUATION OR CONTINUATION-IN-PART APPLICATION IS A PROPER RESPONSE WITH RESPECT TO A PETITION FOR EXTENSION OF TIME OR A PETITION TO REVIVE AND SHOULD INCLUDE THE EXPRESS ABANDONMENT OF THE PRIOR APPLICATION CONDITIONED UPON THE GRANTING OF THE PETITION AND THE GRANTING OF A FILING DATE TO THE CONTINUING APPLICATION.